

AMENDMENT

Please enter the following amendments. Deleted subject matter is indicated with strikethrough text and added subject matter is indicated with underlined text. The current listing of Claims supersedes all previous versions.

IN THE CLAIMS:

1. (Currently Amended) An implantable or insertable medical device comprising a release region, said release region comprising (a) a polymeric carrier comprising a hydrophobic first polymer and (b) drug loaded nanoparticles dispersed within said polymeric carrier, said drug loaded nanoparticles comprising: silicate particles comprising a layered silicate material; ~~and a~~ hydrophilic first therapeutic agent; and a hydrophilic second polymer, wherein the first therapeutic agent ~~and hydrophilic second polymer are~~ is-structurally associated with the silicate particles in that the first therapeutic agent ~~and hydrophilic second polymer occupy~~ occupies spaces between adjacent layers of the silicate material of each silicate particle to form a depot for the first therapeutic agent.
2. (Canceled) ~~The medical device of claim 1, wherein said first therapeutic agent is a hydrophilic therapeutic agent and said first polymer is a hydrophobic polymer.~~
3. (Currently Amended) The medical device of claim ~~2~~ 1, wherein said medical device is a vascular medical device, wherein said first therapeutic agent is halofuginone-HBr, and wherein said first polymer is a polyolefin-polyvinylaromatic block copolymer.
4. (Canceled) ~~The medical device of claim 1, wherein said first therapeutic agent is a hydrophobic therapeutic agent and said first polymer is a hydrophilic polymer.~~
5. (Canceled) ~~The medical device of claim 1, further comprising a second polymer.~~

6. (Canceled) The medical device of claim 5, wherein said polymeric carrier further comprises said second polymer.

7. (Canceled) The medical device of claim 5, wherein said nanoparticles further comprise said second polymer.

8. (Canceled) The medical device of claim 7, wherein said second polymer is hydrophobic and said first polymer is hydrophilic.

9. (Canceled) The medical device of claim 7, wherein said second polymer is hydrophilic and said first polymer is hydrophobic.

10. (Withdrawn and Currently Amended) The medical device of claim 9 ~~6~~, wherein said medical article is a vascular medical device, wherein said first therapeutic agent is halofuginone-HBr, wherein said first polymer is a polyolefin-polyvinylaromatic block copolymer, and wherein said second polymer is a hydrophilic polymer selected from hyaluronic acid, collagen, heparin, chondroitin sulfate, phospho choline, dextran, and polyethylene oxide.

11. (Withdrawn) The medical device of claim 1, wherein said polymeric carrier further comprises said first therapeutic agent.

12. (Withdrawn) The medical device of claim 1, further comprising a second therapeutic agent.

13. (Withdrawn) The medical device of claim 12, wherein said polymeric carrier further comprises said second therapeutic agent.

14. (Withdrawn) The medical device of claim 13, wherein said first therapeutic agent is hydrophilic and said second therapeutic agents is hydrophobic.

15. (Withdrawn) The medical device of claim 12, wherein said nanoparticles further comprise said second therapeutic agent.
16. (Withdrawn) The medical device of claim 15, wherein said first and second therapeutic agents are hydrophilic.
17. (Previously Presented) The medical device of claim 1, wherein said release region is disposed over at least a portion of a medical article substrate.
18. Canceled.
19. (Currently Amended) The medical device of claim ~~18~~ 1, wherein said device is adapted for implantation or insertion into the coronary or peripheral vasculature.
20. (Withdrawn) The medical device of claim 19, wherein said device is adapted for implantation or insertion into the esophagus, trachea, colon, biliary tract, urinary tract, prostate or brain.
21. (Previously Presented) The medical device of claim 19, wherein said device is selected from a catheter, a guide wire, a balloon, a filter, a stent, a stent graft, a vascular graft, a vascular patch, a shunt, an electrode, a heart valve, a circulation pump, and an intraluminal paving system.
22. (Previously Presented) The medical device of claim 19, wherein said therapeutic agent is selected from an anti-thrombotic agent, an anti-proliferative agent, an anti-inflammatory agent, an anti-migratory agent, an agent affecting extracellular matrix production and organization, an antineoplastic agent, an anti-mitotic agent, an anesthetic agent, an anti-coagulant, a vascular cell growth promoter, a vascular cell growth inhibitor, a cholesterol-lowering agent, a vasodilating agent, and an agent that interferes with endogenous vasoactive mechanisms.

23. (Previously Presented) The medical device of claim 1, wherein said layered silicate material comprises synthetic or naturally occurring smectite.

24. (Withdrawn) The medical device of claim 1, wherein said layered silicate material comprises a natural or synthetic silicate material selected from bentonite, aliettite, vermiculite, swinefordite, montmorillonite, yakhontovite, nontronite, beidellite, volkonskoite, stevensite, hectorite, saponite, laponite, sauconite, magadiite, kenyaite and ledikite.

25. (Previously Presented) A method of releasing a therapeutic agent to a patient comprising: (a) providing the medical device of claim 1; and (b) contacting said medical article with a patient.

26. (Withdrawn) A method of providing the medical device of claim 1 comprising:
providing a release-region-forming fluid comprising (a) said first polymer species and (b) said drug loaded nanoparticles; and
applying said release-region-forming fluid to a medical article substrate or to a releasable template.

27. (Previously Presented) The medical device of claim 1 wherein the silicate particles have a maximum cross-sectional length between 30 to 500 nm and spacing between the adjacent layers within the silicate particles is in the range of 5-20Å.

28. (Currently Amended) The medical device of claim 2 ~~1~~ wherein said hydrophobic polymer is selected from the group consisting of olefin polymers and copolymers, styrene polymers and copolymers, halogenated hydrocarbon polymers and copolymers, vinyl polymers and copolymers, polymers and copolymers of acrylic acid esters, polymers and copolymers of methacrylic acid esters, polycarbonates, polyimides, ~~polyetheretherketones~~ ~~polyetheretherketones~~, polyamides, polyvinylacetates, polysulfones, polyethersulfones, polyesters, polyurethanes and siloxane-urethane copolymers, and polyorganosiloxanes.